Patent

SPHINCTER TREATMENT APPARATUS

Related Applications

This application is a divisional of copending
U.S. Application Serial No. 09/776,140, filed February 2,
5   2001, which is a continuation of US application Serial
No. 09/235,060, filed January 20, 1999, now U.S. Patent
No. 6,254,598, which is a continuation-in-part of U.S.
Patent Application Serial No. 09/026,316 filed February
19, 1998, now U.S. Patent No. 6,056,744.

10 ## Field of the Invention

This invention relates generally to an
apparatus for the treatment of sphincters, and more
specifically to an apparatus that treats esophageal
sphincters.

15 ## Description of Related Art

Gastroesophageal reflux disease (GERD) is a
common gastroesophageal disorder in which the stomach
contents are ejected into the lower esophagus due to a
dysfunction of the lower esophageal sphincter (LES).
20 These contents are highly acidic and potentially
injurious to the esophagus resulting in a number of
possible complications of varying medical severity. The
reported incidence of GERD in the U.S. is as high as 10%
of the population (Castell DO; Johnston BT:
25 Gastroesophageal Reflux Disease: Current Strategies For

Patient Management. Arch Fam Med, 5(4):221-7; (1996 April)).

Acute symptoms of GERD include heartburn, pulmonary disorders and chest pain. On a chronic basis, GERD subjects the esophagus to ulcer formation, or esophagitis and may result in more severe complications including esophageal obstruction, significant blood loss and perforation of the esophagus. Severe esophageal ulcerations occur in 20-30% of patients over age 65. Moreover, GERD causes adenocarcinoma, or cancer of the esophagus, which is increasing in incidence faster than any other cancer (Reynolds JC: Influence Of Pathophysiology, Severity, And Cost On The Medical Management Of Gastro esophageal Reflux Disease. Am J Health Syst Pharm, 53(22 Suppl 3):S5-12 (1996 Nov 15)).

One of the possible causes of GERD may be aberrant electrical signals in the LES or cardia of the stomach. Such signals may cause a higher than normal frequency of relaxations of the LES allowing acidic stomach contents to be repeatedly ejected into the esophagus and cause the complications described above. Research has shown that unnatural electrical signals in the stomach and intestine can cause reflux events in those organs (Kelly KA, et al: Duodenal-gastric Reflux and Slowed Gastric Emptying by Electrical Pacing of the Canine Duodenal Pacesetter Potential. Gastroenterology. 1977 Mar; 72(3): 429-433). In particular, medical research has found that sites of aberrant electrical activity or electrical foci may be responsible for those signals (Karlstrom LH, et al.: Ectopic Jejunal Pacemakers and Enterogastric Reflux after Roux Gastrectomy: Effect Intestinal Pacing. Surgery. 1989 Sep; 106(3): 486-495). Similar aberrant electrical sites in the heart which cause contractions of the heart muscle to take on life threatening patterns or dysrhythmias can be identified

and treated using mapping and ablation devices as described in US Patent No. 5,509,419. However, there is no current device or associated medical procedure available for the electrical mapping and treatment of aberrant electrical sites in the LBS and stomach as a means for treating GERD.

Current drug therapy for GERD includes histamine receptor blockers which reduce stomach acid secretion and other drugs which may completely block stomach acid. However, while pharmacologic agents may provide short term relief, they do not address the underlying cause of LES dysfunction.

Invasive procedures requiring percutaneous introduction of instrumentation into the abdomen exist for the surgical correction of GERD. One such procedure, Nissen fundoplication, involves constructing a new "valve" to support the LES by wrapping the gastric fundus around the lower esophagus. Although the operation has a high rate of success, it is an open abdominal procedure with the usual risks of abdominal surgery including: postoperative infection, herniation at the operative site, internal hemorrhage and perforation of the esophagus or of the cardia. In fact, a recent 10 year, 344 patient study reported the morbidity rate for this procedure to be 17% and mortality 1% (Urschel, JD: Complications Of Antireflux Surgery, Am J Surg 166(1): 68-70; (1993 July)). This rate of complication drives up both the medical cost and convalescence period for the procedure and may exclude portions of certain patient populations (e.g., the elderly and immuno-compromised).

Efforts to perform Nissen fundoplication by less invasive techniques have resulted in the development of laparoscopic Nissen fundoplication. Laparoscopic Nissen fundoplication, reported by Dallemagne et al. Surgical Laparoscopy and Endoscopy, Vol. 1, No. 3, (1991),

pp. 138-43 and by Hindler et al. Surgical Laparoscopy and Endoscopy, Vol.2, No.3, (1992), pp. 265-272, involves essentially the same steps as Nissen fundoplication with the exception that surgical manipulation is performed through a plurality of surgical cannula introduced using trocars inserted at various positions in the abdomen.

Another attempt to perform fundoplication by a less invasive technique is reported in U.S. Patent No. 5,088,979. In this procedure an invagination device containing a plurality of needles is inserted transorally into the esophagus with the needles in a retracted position. The needles are extended to engage the esophagus and fold the attached esophagus beyond the gastroesophageal junction. A remotely operated stapling device, introduced percutaneously through an operating channel in the stomach wall, is actuated to fasten the invaginated gastroesophageal junction to the surrounding involuted stomach wall.

Yet another attempt to perform fundoplication by a less invasive technique is reported in US Patent No. 5,676,674. In this procedure, invagination is done by a jaw-like device and fastening of the invaginated gastroesophageal junction to the fundus of the stomach is done via a transoral approach using a remotely operated fastening device, eliminating the need for an abdominal incision. However, this procedure is still traumatic to the LES and presents the postoperative risks of gastroesophageal leaks, infection and foreign body reaction, the latter two sequela resulting when foreign materials such as surgical staples are implanted in the body.

While the methods reported above are less invasive than an open Nissen fundoplication, some still involve making an incision into the abdomen and hence the increased morbidity and mortality risks and convalescence

period associated with abdominal surgery. Others incur the increased risk of infection associated with placing foreign materials into the body. All involve trauma to the LES and the risk of leaks developing at the newly

5   created gastroesophageal junction.

Besides the LES, there are other sphincters in the body which if not functionally properly can cause disease states or otherwise adversely affect the lifestyle of the patient. Reduced muscle tone or

10   otherwise aberrant relaxation of sphincters can result in a laxity of tightness disease states including, but not limited to, urinary incontinence.

There is a need to provide an apparatus to treat a sphincter and reduce a frequency of sphincter

15   relaxation. Another need exists for an apparatus to create controlled cell necrosis in a sphincter tissue underlying a sphincter mucosal layer. Yet another need exists for an apparatus to create cell necrosis in a sphincter and minimize injury to a mucosal layer of the

20   sphincter. There is another need for an apparatus to controllably produce lesions in a sphincter without creating a permanent impairment of the sphincter's ability to achieve a physiologically normal state of closure. Still a further need exists for an apparatus to

25   create a tightening of a sphincter without permanently damaging anatomical structures near the sphincter. There is still another need for an apparatus to create cell necrosis in a lower esophageal sphincter to reduce a frequency of reflux of stomach contents into an

30   esophagus.

Summary of the Invention

Accordingly, an object of the present invention is to provide an apparatus to treat a sphincter and reduce a frequency of sphincter relaxation.

35   Another object of the invention is to provide

an apparatus to create controlled cell necrosis in a sphincter tissue underlying a sphincter mucosal layer.

Yet another object of the invention is to provide an apparatus to create cell necrosis in a sphincter and minimize injury to a mucosal layer of the sphincter.

A further object of the invention is to provide an apparatus to controllably produce a lesion in a sphincter without creating a permanent impairment of the sphincter's ability to achieve a physiologically normal state of closure.

Still another object of the invention is to provide an apparatus to create a tightening of a sphincter without permanently damaging anatomical structures near the sphincter.

Another object of the invention is to provide an apparatus to create cell necrosis in a lower esophageal sphincter to reduce a frequency of reflux of stomach contents into an esophagus.

Yet another object of the invention is to provide an apparatus to reduce the frequency and severity of gastroesophageal reflux events.

These and other objects of the invention are provided in a sphincter treatment apparatus. The apparatus includes an elongated member with lumen and a basket assembly with first and second arms. The basket assembly is coupled to the elongated member and has deployed and non-deployed configurations. An inflatable member is coupled to the elongated member and positioned in an interior of state, the inflatable member expands the basket assembly to its deployed configuration. A first energy delivery device is positionable in the first arm and advanceable from the first arm to a selected treatment site. A second energy delivery device is positionable in the second arm and advanceable from the

second arm to a selected treatment site.the basket assembly. The inflatable member has deployed and non-deployed states and is coupled to the elongated member lumen. In the deployed state, the inflatable member

5   expands the basket assembly to its deployed configuration. A first energy delivery device is positionable in the first arm and advanceable from the first arm to a selected treatment site. A second energy delivery device is positionable in the second arm and

10   advanceable from the second arm to a selected treatment site.

Brief Description of the Drawings

        Figure 1 is an illustrated lateral view of the upper GI tract including the esophagus and lower

15   esophageal sphincter and the positioning of the sphincter treatment apparatus of the present invention in the lower esophageal sphincter.

        Figure 2a is a cross-sectional view of one embodiment of the present invention illustrating the

20   inflatable member, the delivery of energy from the basket assembly and advancement of an elongated medical device through a lumen of the elongated member.

        Figure 2b is a perspective view of an embodiment of the invention illustrating the use of

25   lumens and tubes in the basket arms.

        Figure 2c is a perspective view illustrating an embodiment of the invention where the energy delivery devices are deployed in multi-level geometries.

        Figure 2d is a cross-sectional view

30   illustrating the attachment of energy delivery devices to the basket arms and balloon.

        Figure 2e is a cross-sectional view illustrating an energy delivery device comprising a conductive coating on or in the balloon.

35   Figure 2f is a cross-sectional view

illustrating the use of needles as RE energy delivery devices, including the use of hollow and insulated needles.

Figure 2g is a cross-sectional view illustrating the use of a drug delivery device and medicament coupled to the apparatus of Figure 2A.

Figure 3 is a cross-sectional view illustrating the creation of lesions in a sphincter using the apparatus of Figure 2A.

Figure 4 is a cross-sectional view illustrating the use of a cooling media and its introduction via the basket arms or energy delivery devices.

Figure 5a is a cross-sectional view of an embodiment of the apparatus where the balloon has a deployed, non-circular, cross-sectional geometry that provides for the creation of axial flow channels adjacent to an exterior of the sphincter.

Figure 5b is a cross-sectional view of an embodiment where the balloon has a pear shape.

Figures 5c and 5d are cross-sectional views of embodiments of the invention where the balloon has a Cassini oval dogbone and oval shape.

Figure 6 is a cross-sectional view illustrates deployment of a balloon which has an elongated, substantially non-tapered geometry.

Figure 7 is a cross-sectional view of the apparatus of Figure 2A illustrating the coupling of an energy delivery device advancement and retraction member.

Figure 8 is a cross-sectional view of an arm of the apparatus of Figure 2A where all of the energy delivery devices positioned in the arm are advanced and retracted by a single advancement member.

Figure 9 is a cross-sectional view illustrating an embodiment of the invention having an

insulated lumen that carries individual power wires that are coupled to separate energy delivery devices.

Figures 10a and 10b are cross-sectional views illustrating the use of over indexing with an advancement mechanism to reduce the occurrence of tenting during needle insertion into sphincter wall tissue.

Figure 10c is a cross-sectional view of an embodiment of the advancement mechanism utilizing mechanical stops and springs.

Figure 11 is a flow chart illustrating a sphincter treatment method using the apparatus of the present invention.

Figure 12 is a cross-sectional view of a multi-channel RF generator useful with the apparatus of Figure 2A.

Figure 13 is a cross-sectional view of an RF generator that sequentially delivers energy to distinct RF electrodes.

Figure 14 depicts a block diagram of a feed back control system that can be used with the sphincter treatment apparatus of the present invention.

Figure 15 depicts a block diagram of an analog amplifier, analog multiplexer and microprocessor used with the feedback control system of Figure 14.

Figure 16 depicts a block diagram of the operations performed in the feedback control system of Figure 14.

Detailed Description

Referring now to Figure 1, one embodiment of sphincter treatment apparatus 10 is illustrated. Apparatus 10 delivers energy to a treatment site 12 to produce lesions 14 in a sphincter 16, such as the lower esophageal sphincter (LES) having a wall 17 and mucosal layers 17'. Apparatus 10 includes a flexible elongate shaft 18 which can be an introducer, cannula, catheter

and the like.

As illustrated in Figure 2a, shaft 18 is coupled to a basket assembly 20. Basket assembly 20 is made of a plurality of arms 21. A plurality of energy delivery devices 22 are positioned and advanced from arms 21 into different circumferential regions of tissue site 12 or other treatment site within the sphincter wall 17 or adjacent anatomical structure. Energy delivery devices 22 are positioned, advanceable and retractable to and from basket assembly 20. Energy delivery devices 22 are positioned a desired depth in a sphincter wall 17 or adjoining anatomical structure. Energy delivery devices 22 are configured to be coupled to an energy source 24. An inflatable or expandable member 25 is also coupled to shaft 18 and is preferably an inflatable balloon well known in the art. Balloon 25 is positioned within the interior of basket assembly 20.

Shaft 18 has a proximal and distal end 18' and 18" and has sufficient length to position expandable basket assembly 20 in the LES and/or stomach including the cardia using a transoral approach. Typical lengths for shaft 18 include, but are not limited to, a range of 40-180 cms. In various embodiments, shaft 18 is flexible, articulated and steerable and can contain fiber optics (including illumination and imaging fibers), fluid and gas paths, and sensor and electronic cabling. In one embodiment, shaft 18 can be a multi-lumen catheter, as is well known to those skilled in the art. Shaft 18 cam also be coupled to a proximal handle 31, which in various embodiments can include handle ports 31' for balloon inflation, and the delivery of cooling and other fluids described herein. Ports 31' can include but are not limited to valves (one-way or two-way), luer fittings and other adaptors and medical fittings known in the art.

Basket assembly 20 is configured to be

positionable in a sphincter 16 such as the LES or
adjacent anatomical structure, such as the cardia of the
stomach. Basket assembly 20 has a central longitudinal
axis 20' and is moveable between contracted and expanded
5   positions (also called non-deployed and deployed
configurations) substantially there along. In various
embodiments, this can be accomplished without a balloon
using a pullwire mechanism (not shown) which can include
a ratchet mechanism for locking the pull wire in given
10   position. At least portions of apparatus 10 may be
sufficiently radiopaque in order to be visible under
fluoroscopy and/or sufficiently echogenic to be visible
under ultrasonography. Also as will be discussed herein,
apparatus 10 can include visualization capability
15   including, but not limited to, a viewing scope, an
expanded eyepiece, fiber optics, video imaging and the
like. Such viewing means may be delivered through a
central lumen 19 within elongated shaft 18 or within or
alongside basket assembly 20. In various embodiments,
20   elongated shaft 18 may have multiple lumens 19 which can
be configured for the advancement of various elongated
medical devices 23 to a treatment site 12 or other area
in the body. Elongated medical devices 23 can include
guidewires, drug delivery catheters, manometry catheters,
25   pH monitoring catheters, endoscopes, viewing scopes and
the like. Lumens 19 can also be configured for the
delivery of liquids (including cooling liquids), gases
and drugs or medicaments 13 to a treatment site 12 or
other area of the body. In one embodiment lumen 19 can be
30   configured as an inflation lumen described herein to
inflate inflatable member 25 using a liquid or gaseous
inflation media.

Referring now to Figure 2b, arms 21 can have
one or more channels or lumens 21' or may comprise
35   multiple tubes 21" to allow multiple functions to be

performed at each arm such as needle deployment and the
delivery of cooling or electrolytic fluids. Also, arms 21
may form a variety of geometric shapes including, but not
limited to, curved, rectangular, trapezoidal and
triangular. Arms 21 can also have any number of different
cross sectional geometries including, but not limited to,
circular, rectangular and crescent-shaped. In one
embodiment, arms 21 are of a sufficient number, such as
two or more, and with adequate spring force (0.01 to 0.5
lbs. force) to collectively exert enough force on the
sphincter wall 17 to open and efface the folds of
sphincter 16. Arms 21 can be made of a variety of
different materials including but not limited to, spring
steel, stainless steel, superelastic shape memory metals
such as nitinol, un- reinforced plastic tubing, or wire
reinforced plastic tubing as is well known to those
skilled in the art. Arms 21 can also have an outwardly
bowed shaped memory for expanding basket assembly 20 into
engagement with the sphincter wall, with the amount of
bowing or camber 20" being selectable. Aims 21 may be
preshaped at time of manufacture or shaped by the
physician.

In another embodiment, arms 21 may have an
external layer of the texturized material that has
sufficient friction to at least partially immobilize the
area of sphincter wall near and around that contacted by
an arm 21. Suitable materials for the texturized material
include knitted Dacron® and Dacron velour.

In one embodiment, illustrated in Figure 2c,
energy delivery devices 22 are deployed in multi-level
geometries. As shown, first, second and third levels of
energy delivery devices 22', 22" and 22''' are deployed.
The energy delivery devices 22 of each level define a
plane of deployment 33 which can include first second and
third deployment planes 33', 33" and 33'''. Each plane of

deployment for the different multi-levels can be parallel. In various embodiments, first, second and third levels of energy delivery devices 22', 22" and 22''' are deployed simultaneously or alternatively sequentially.

5   Turning now to a discussion of energy delivery, suitable energy sources 24 and energy delivery devices 22 that can be employed in one or more embodiments of the invention include: (i) a radio-frequency (RF) source coupled to an RF electrode, (ii) a

10   coherent source of light coupled to an optical fiber, (iii) an incoherent light source coupled to an optical fiber, (iv) a heated fluid coupled to a catheter with a closed channel configured to receive the heated fluid, (v) a heated fluid coupled to a catheter with an open

15   channel configured to receive the heated fluid, (vi) a cooled fluid coupled to a catheter with a closed channel configured to receive the cooled fluid, (vii) a cooled fluid coupled to a catheter with an open channel configured to receive the cooled fluid, (viii) a

20   cryogenic fluid, (ix) a resistive heating source coupled to a heating element positioned either on the arms to heat tissue directly or within the balloon to heat the inflation medium, (x) a microwave source providing energy from 915 MHz to 2.45 GHz and coupled to a microwave

25   antenna, or (xi) an ultrasound power source coupled to an ultrasound emitter, wherein the ultrasound power source produces energy in the range of 300 KHZ to 3 GHz. For ease of discussion for the remainder of this specification, the power source utilized is an RF source

30   and energy delivery device 22 is one or more RF electrodes 22. However, all of the other herein mentioned energy sources and energy delivery devices are equally applicable to sphincter treatment apparatus 10.

          For the case of RF energy, RF electrode 22 may

35   be operated in either bipolar or monopolar mode with a

ground pad electrode. In a monopolar mode of delivering RF energy, a single electrode 22 is used in combination with an indifferent electrode patch that is applied to the body to form the other electrical contact and
5 complete an electrical circuit. Bipolar operation is possible when two or more electrodes 22 are used. Electrodes 22 can be attached to an electrode delivery member (describe herein) by the use of soldering methods which are well known to those skilled in the art.
10 Suitable solders include Megabond Solder supplied by the Megatrode Corporation (Milwaukee, Wisconsin). Other joining methods include, but are not limited to, welding and adhesive bonding (including the use of conductive adhesives known in the art). In various embodiments, the
15 electrode to delivery member joint can be conductive (for the case where electrodes 22 are activated simultaneously) or nonconductive (for the case where electrodes 22 are activated individually). In the latter case, electrodes are attached to individual conductors
20 and are electrically isolated from each other (e.g. other electrodes).

Referring now to Figures 2d and 2e, in other embodiments, electrodes 22 can be attached to arms 21, or balloon 25 using adhesive bonding or other joining
25 methods known in the art. In one embodiment all or a portion of electrodes 22 can integral to or otherwise built into arms 21. This can be accomplished using a variety of plastic processing methods known in the art including, the use of heated capture tubes and/or heated
30 collets or notching fixtures. In one embodiment, electrodes 22 can be substantially flush with the surface of arms 21. Electrodes 22 can also be attached to the exterior surface 25' of balloon 25. In one embodiment shown in Figure 2e, electrode 22 may comprise a
35 conductive coating or layer 25" that is applied to all or

a portion of the or exterior 25' or interior 25" surface of balloon 25 or is otherwise incorporated/embedded into the wall of balloon 25. Coating 25''' may include conductive polymers or metals (e.g. gold, platinum, etc.) and may applied using, sputtering, spraying or electro/chemical deposition techniques known in the art. In one embodiment, conductive coating 25''' can be applied to discrete areas on the exterior surface 25' of balloon 25 using masking and electro/chemical deposition techniques known in the art.

RF electrodes 22 can have a variety of shapes and sizes. Possible shapes include, but are not limited to, circular, rectangular, conical and pyramidal. Electrode surfaces can be smooth or textured and concave or convex. The conductive surface area of electrode 22 can range from 0.1 cm2 to 100 cm2. It will be appreciated that other geometries and surface areas may be equally suitable.

Referring now to Figure 2f in one embodiment, RF electrodes 22 can be in the shape of needles and of sufficient sharpness and length to penetrate into the smooth muscle of the esophageal wall, sphincter 16 or other anatomical structure. An insulation sleeve 27 can be positioned at an exterior of each RF electrode 22. The use of insulation sleeve 27 creates an insulated segment 27' of RF electrode 22 and provides protection of the mucosal layer 17' of sphincter 16. For purposes of this disclosure, an insulator or insulation layer is a barrier to either thermal, RF or electrical energy flow. The insulated segment of RF electrode 22 is of sufficient length to extend into the sphincter wall 17 and minimize transmission of RF energy to a protected site 12' near or adjacent to insulated segment 27'. Typical lengths for insulated segment 27' include, but are not limited to, 1-8 mms, with preferred embodiments of 2, 5 and 8 mms.

Typical lengths for the uninsulated portion or segment 27" of electrode 22 include 2 to 6 mms, with preferred embodiments of 3,4 and 5 mms.

Suitable materials for RF electrodes 22 include, but are not limited to, 304 stainless steel and other stainless steels known to those skilled in the art. Suitable materials for insulation sleeve 27 include, but are not limited to, polyimides and parylene; and in a preferred embodiment, PET (polyethylene terephthalate).

Referring back to Figure 2a, balloon 25 can be coupled to and inflated by an inflation lumen 26 (which can also be lumen 19) using gas or liquid as is known in the art. This results in balloon 25 going from an non-deployed to a deployed state. Inflation lumen 26 can be coupled to handle port 31' which can be a one-way valve known in the art. All or a portion of balloon 25 can be made of a non compliant material (as is known in the art) in order to achieve a predictable fixed balloon diameter. In various embodiments, such non compliant materials include PET, irradiated polyethylene, polyurethane and others known in the art. In alternative embodiments, balloon 25 can be configured to have an adjustable diameter by constructing all or a portion of balloon 25 from compliant materials. Such compliant materials include latex, silicone, C-flex and other thermoplastics and elastomers known in the art. All or a portion of balloon 25 may be made of a textured material, or have a texturized layer that when engaged with a sphincter wall 17 provides sufficient friction to at least partially immobilize the surface of the sphincter wall. Suitable materials for the texturized layer include knitted Dacron® and Dacron velour.

Referring now to Figure 2g, apparatus 10 can also be configured to be coupled to a medical device 23' including a drug delivery device, 23'. In various

embodiments, drug delivery device 23' can include an infusion pump, syringe (manual or motorized) IV bag with a pressure clamp or other drug delivery device known in the art. Drug delivery device 23' can also be coupled to
5   medicament 13 and or medicament reservoir 13' containing medicament 13.

        Referring now to Figure 3, energy delivery devices 22 are advanced into sphincter wall 17 a sufficient distance to create lesions 14 while preserving
10   sphincter mucosal layer 17'. In one embodiment, lesions 14 are created circumferentially and equally distanced in order to create an even tightening of sphincter 16. In another embodiment, lesions are created that are about 1 mm below the surface of sphincter wall mucosal layer 17'
15   and extend to a depth of about 4mm within sphincter wall 17.

        Referring now Figure 4, a fluidic media 35, including but not limited to, a cooling media 35, can be introduced through arms 21. Cooling media 35 is
20   introducible through ports 21''' or apertures 21''' from which energy delivery devices 22 are advanced or through distinct and separate apertures 21'''. Arms 21 can be fluidically coupled to cooling media 35 and/or a cooling media reservoir 35' via arm lumens 21'. Other suitable
25   fluidic media 35 include, but are not limited to, sterile water, saline, anti-infective agents, echogenic media, steroids, local anesthetics and the like. The use of cooling preserves the mucosal layers 17' of sphincter 16 and protects, or otherwise reduces the degree of cell
30   damage in the vicinity of lesion 14.

        Similarly, it may also be desirable to cool all or a portion of RF electrode 22. The rapid delivery of heat through RF electrodes 22 may result in the build up of charred biological matter on RF electrodes 22 (from
35   contact with tissue and fluids e.g., blood) that impedes

the flow of both thermal and electrical energy from RF
electrodes 22 to adjacent tissue and causes an electrical
impedance rise beyond a cutoff value set on RF energy
source 24. A similar situation may result from the
5 desiccation of tissue adjacent to RF electrodes 22.
Cooling of RF electrodes 22 can be accomplished by the
use of cooling media 35.

Additionally, electrodes 22 can be hollow and
used to introduce electrolytic solutions into sphincter
10 16 and sphincter wall 17 through the use of ports 21'''
disposed on electrodes 22 that are fluidically coupled to
cooling media 35 and/or cooling media reservoir 35'.
Suitable electrolytic solutions include saline; and
solutions of calcium salts, potassium salts, and the
15 like. Electrolytic solutions enhance the electrical
conductivity of the targeted tissue at the treatment site
12. When a highly conductive fluid such as an
electrolytic solution is infused into tissue the
electrical resistance of the infused tissue is reduced,
20 in turn, increasing the electrical conductivity of the
infused tissue. As a result, there is little tendency for
tissue surrounding RF electrode 22 to desiccate (a
condition described herein that increases the electrical
resistance of tissue) resulting in a large increase in
25 the capacity of the tissue to carry RF energy.

One or more sensors 29 may be positioned
adjacent to or on RF electrode 22 for sensing the
temperature of sphincter tissue at treatment site 12.
More specifically, sensors 29 permit accurate
30 determination of the surface temperature and/or interior
temperature of sphincter 16. This information can be used
to regulate both the delivery of energy and cooling media
35 to sphincter 16. In various embodiments, sensors 29
can be positioned at any position on balloon 25, basket
35 assembly 20 or at an RF electrode 22. Suitable sensors

that may be used include but are not limited to, thermocouples, fiber optics, resistive wires, thermocouple IR detectors, and the like. Suitable thermocouples include T type with copper constantene, J

5   type, F type and K types as are well known those skilled in the art.

As illustrated in Figure 5a-5d, balloon 25 can have a variety of different deployed geometric configurations. Such configurations include, but are not

10   limited to, spherical, football-shaped, cylindrical, channeled dog bone, oval and pear shapes. In the embodiment illustrated in Figure 5a, balloon 25 has a non-circular cross-section which creates axial channels 30 between an exterior surface 25' of balloon 25 and

15   sphincter 16. Axial channels 30 provide for the flow (in both proximal and distal directions) of any suitable fluid or media, such as a cooling media 35, at the interior surface of sphincter wall 17. In the embodiment illustrated in Figure 5b, balloon 25 can be at least

20   partially pear-shaped to approximately match the shape of the cardia of the stomach. In embodiments illustrated in Figures 5c and 5d, balloon 25 can have a Cassini oval shape, including embodiments where the Cassini oval has a dog bone (Figure 5c) shape or oval shape (Figure 5d). The

25   dog bone shape facilitates maintaining the position of balloon 25 in a sphincter such as the LES or other stricture.

Another geometric configuration of balloon 25 is illustrated in Figure 6. In this embodiment, balloon

30   25 has a substantially uniform interface surface 39 with sphincter wall 17. This uniformity provides substantially even contact between arms 21 and sphincter wall 17 in order to create uniform lesion 14 creation.

Referring now to Figure 7, an electrode

35   advancement and retraction member 32 (also called an

electrode delivery member) is coupled to RF electrodes 22. In various embodiments electrode advancement and retraction member 32 can be an insulated wire, an insulated guide wire, a plastic-coated stainless steel

5   hypotube with internal wiring or a plastic catheter with internal wiring, all of which are known to those skilled in the art. Retraction member 32 can also have a pre-shaped curve that can be directed by torquing member 32 or can be actively deflectable via the use of a pullwire

10   or other mechanisms known in the art. Lumen 19 and retraction member 32 can be configured such that retraction member 32 is advanceable within lumen 19.

In one embodiment, all RF electrodes 22 can be coupled to the same electrode advancement and retraction

15   member 32. Alternatively, various numbers and groups of RF electrodes can be coupled to different electrode advancement and retraction members 32. In the embodiment illustrated in Figure 8, all HF electrodes 22 in an arm 21 are coupled to the same electrode advancement and

20   retraction member 32 and as such, can be advanced into sphincter 16 simultaneously. In this and related embodiments, retraction member 32 can be employed so as to produce multiple lesions 14 in the sphincter wall 17 while maintaining apparatus 10, in a substantially

25   stationary position within sphincter 16. The configuration and use of retraction member 32 in this manner provides the advantage of reduced procedure time and a reduced likelihood of any trauma to the esophagus and surrounding tissue due to a reduced need to

30   manipulate the apparatus within the esophagus.

Referring now to Figure 9, each RF electrode 22 can be coupled to a separate power wire 34 that is coupled to energy source 24. This permits RF electrodes to deliver energy non-simultaneously and offers the

35   following advantages: i) individually tailored power

delivery for each electrode, ii) individually temperature control for each electrode, iii) ability to compensate for differences in local tissue characteristics (e.g. electrical impedance, morphology, etc.) adjacent each electrode or variations in electrode penetration depth for the use of multiple electrodes, iv) more precise control of lesion location and size, v) generation of eccentric lesions or otherwise varying lesion locations and sizes, and vi) reduced procedure time. In alternative embodiments, energy delivery by multiple electrodes can be performed simultaneously through separate RF electrodes by utilizing a multichannel RF generator or by multiplexing the delivery of RF energy from a single RF energy source 24 to multiple RF electrodes 22 using multiplexing circuitry well known in the art. In still other embodiments, RF energy can be delivered sequentially to different electrode using a simple switch box known in the art.

Also when the energy source is RF, energy source 24, which will now be referred to as RF energy source 24, may have multiple channels, delivering separately modulated power to each RF electrode 22. This configuration reduces preferential heating that occurs when more energy is delivered to a zone of greater conductivity and less heating occurs around RF electrodes 22 which are placed into less conductive tissue. If the level of tissue hydration or the blood infusion rate in the tissue is uniform, a single channel RF energy source 24 may be used to provide power for generation of lesions 14 relatively uniform in size.

During introduction of apparatus 10, basket assembly 20 is in a contracted or non-deployed state. Once apparatus 10 is properly positioned at the treatment site 12, balloon 25 is inflated, basket assembly 20 is deployed (expanded) and HF electrodes 22 are then

introduced into sphincter wall 17. The depth of needle penetration is selectable from a range of about 0.5 to 5 mms and can be accomplished by an indexed movable fitting coupled to shaft 18.

5   Referring now to Figures 10a and 10b, in another embodiment electrodes or needles 22 can be initially over-indexed to puncture through sphincter wall tissue to a first position and then retracted to a second or detent position where the needle tip is well within a

10 desired penetration depth range in the esophageal wall tissue (e.g. 1-4 mms) for safe and effective tissue ablation of the desired treatment site 12. Such a configuration has the advantage of reducing or eliminating the occurrence of "tenting' of esophageal

15 and/or sphincter tissue that may occur during electrode needle penetration. In these and related embodiments, the advancement of electrode 22 can be controlled by the use of an electrode advancement mechanism 37 or fixture 37. As shown in Figures 10a and 10b, advancement mechanism 37

20 can include a ratchet mechanism or indexing mechanism, and the like. Alternatively as shown in Figure 10c, mechanism 37 can include the use of a combination of mechanical stops and springs disposed in arm 21. In still other embodiments, mechanism 37 can include a combination

25 one or more of the following: springs, stops, a ratchet mechanism or indexing mechanism. In various embodiments, advancement mechanism 37 can also be positioned at the proximal end 18' of the elongated shaft 18, on or within handpiece 31 or within arm 21.

30   RF energy flowing through sphincter or other tissue causes heating of the tissue due to absorption of the RF energy by the tissue and ohmic heating due to electrical resistance of the tissue. This heating can cause injury to the affected cells which can be

35 substantial enough to cause cell death, a phenomenon also

known as cell necrosis. For ease of discussion for the remainder of this application, cell injury will include all cellular effects resulting from the delivery of energy from RF electrode 22 up to, and including, cell

5   necrosis. Cell injury can be accomplished as a relatively simple medical procedure with local anesthesia. In one embodiment, cell injury proceeds to a depth of approximately 1-4 mms from the surface of the mucosal layer 17' of sphincter 16 or that of an adjoining

10   anatomical structure.

Figure 11 is a flow chart illustrating one embodiment of the procedure for using apparatus 10. In this embodiment, apparatus 10 is first introduced into the esophagus under local anesthesia. Apparatus 10 can be

15   introduced into the esophagus by itself or through a lumen in an endoscope (not shown), such as disclosed in U.S. Patents Nos. 5,448,990 and 5,275,608, both incorporated herein by reference, or similar esophageal access device known to those skilled in the art. Basket

20   assembly 20 is expanded. Once introduced, basket assembly 20 is deployed by inflation of balloon 25 or other means. This serves to temporarily dilate the LES or sufficiently to efface a portion of or all of the folds of the LES. In an alternative embodiment, esophageal dilation and

25   subsequent LES fold effacement can be accomplished by insufflation of the esophagus (a known technique) using gas introduced into the esophagus. Once treatment is completed, basket assembly 20 is returned to its predeployed or contracted state and apparatus 10 is

30   withdrawn from the esophagus. This results in the LES returning to approximately its pretreatment state and diameter. It will be appreciated that the above procedure is applicable in whole or part to the treatment of other sphincters in the body.

35   The diagnostic phase of the procedure can be

performed using a variety of diagnostic methods, including, but not limited to, the following: (i) visualization of the interior surface of the esophagus via an endoscope or other viewing apparatus inserted into

5   the esophagus, (ii) visualization of the interior morphology of the esophageal wall using ultrasonography to establish a baseline morphology for the tissue to be treated, (iii) impedance measurement to determine the electrical conductivity between the esophageal mucosal

10   layers 17' and apparatus 10, (iv) esophageal pressure measurement to determine location of the LES using esophageal manometry methods which may include the use of a manometry catheter and measurement system such as that sold by Medtronic Synectics (Stockholm, Sweden), (v)

15   measurement and surface mapping of the electropotential of the LES during varying time periods which may include such physiological events as depolarization, contraction and repolarization of LES smooth muscle tissue. This latter technique is done to determine target treatment

20   sites 12 in the LES or adjoining anatomical structures.

         In the treatment phase of the procedure, the delivery of energy to treatment site 12 can be conducted under feedback control, manually or by a combination of both. Feedback control (described herein) enables

25   apparatus 10 to be positioned and retained in the esophagus during treatment with minimal attention by the physician. RF electrodes 22 can be multiplexed in order to treat the entire targeted treatment site 12 or only a portion thereof. Feedback can be included and is achieved

30   by the use of one or more of the following methods: (i) visualization, (ii) impedance measurement, (iii) ultrasonography, (iv) temperature measurement; and, (v) sphincter contractile force (e.g. pressure) measurement via manometry. The feedback mechanism permits the

35   selected on-off switching of different RF electrodes 22

in a desired pattern, which can be sequential from one RF
electrode 22 to an adjacent RF electrode 22, or can jump
around between non-adjacent RF electrodes 22. Individual
RF electrodes 22 can be multiplexed and volumetrically
5   controlled by a controller.

The area and magnitude of cell injury in the
LES or sphincter 16 can vary. However, it is desirable to
deliver sufficient energy to the targeted treatment site
12 to be able to achieve tissue temperatures in the range
10   of 55-95°C and produce lesions 14 at depths ranging from
1-4 mms from the interior surface of the LES or sphincter
wall 17. Typical energies delivered to the sphincter wall
17 include, but are not limited to, a range between 100
and 50,000 joules per RF electrode 22. It is also
15   desirable to deliver sufficient energy such that the
resulting lesions 14 have a sufficient magnitude and area
of cell injury to cause an infiltration of lesion 14 by
fibroblasts, myofibroblasts, macrophages and other cells
involved in the tissue healing process. These cells cause
20   a contraction of tissue around lesion 14, decreasing its
volume and/or altering the biomechanical properties at
lesion 14 so as to result in a tightening of LES or
sphincter 16.

From a diagnostic standpoint, it is desirable
25   to image the interior surface and wall 17 of the LES or
other sphincter 16, including the size and position of
created lesions 14. A map of these lesions 14 can
inputted to a controller and used to direct the delivery
of energy to the treatment site. This can be accomplished
30   through the use of ultrasonography (a known procedure)
which involves the use of an ultrasound energy source
coupled to one or more ultrasound transducers that can be
positioned on balloon 25 or basket assembly 20. An output
is associated with the ultrasound energy source.
35   It is desirable that lesions 14 be

predominantly located in the smooth muscle layer of
selected sphincter 16 at the depths ranging from 1 to 4
mms from the interior surface of sphincter wall 17.
However, lesions 14 can vary both in number and position
5   within sphincter 16. It may be desirable to produce a
pattern of multiple lesions 14 within the sphincter
smooth muscle tissue in order to obtain a selected degree
of tightening of the LES or other sphincter 16. Typical
lesion patterns include, but are not limited to, (i) a
10   concentric circle of lesions 14 formed at different
levels in the smooth muscle layer evenly spaced along the
radial axis of sphincter 16, (ii) a wavy or folded circle
of lesions 14 at varying depths in the smooth muscle
layer evenly spaced along the radial axis of sphincter
15   16, (iii) lesions 14 randomly distributed at varying
depths in the smooth muscle, but evenly spaced in a
radial direction; and, (iv) an eccentric pattern of
lesions 14 in one or more radial locations in the smooth
muscle wall. Accordingly, the depth of RF and thermal
20   energy penetration sphincter 16 is controlled and
selectable. The selective application of energy to
sphincter 16 may be the even penetration of RF energy to
the entire targeted treatment site 12, a portion of it,
or applying different amounts of RF energy to different
25   sites depending on the condition of sphincter 16. If
desired, the area of cell injury can be substantially the
same for every treatment event.

Referring now to Figure 12, RF energy source
24 can include independent RF channels 24' that operate
30   in parallel and are coupled to different RF electrodes
22. As illustrated in Figure 13, RF energy source 24 can
be configured (using circuitry known in the art such as a
multiplexing circuit) to deliver energy to multiple RF
electrodes 22 in a time-sharing fashion. This permits the
35   delivery of RF energy to individual RF electrodes 22 for

a selected period of time to each RF electrode 22 in a sequential manner.

In one embodiment, apparatus 10 is coupled to an open or closed loop feedback system. Referring now to 5 Figure 14, an open or closed loop feedback system couples sensor 129 to energy source 124. In this embodiment, RF electrode 122 is one or more RF electrodes 122.

The temperature of the sphincter wall tissue, or of RF electrode 122 is monitored, and the output power 10 of energy source 124 adjusted accordingly. The physician can, if desired, override the closed or open loop system. A microprocessor 136 can be included and incorporated in the closed or open loop system to switch power on and off, as well as modulate the power. The closed loop 15 system utilizes microprocessor 136 to serve as a controller 138, monitor the temperature, adjust the RF power, analyze the result, refeed the result, and then modulate the power.

With the use of sensor 129 and the feedback 20 control system a tissue adjacent to RF electrode 122 can be maintained at a desired temperature for a selected period of time without causing a shut down of the power circuit to RF electrode 122 due to the development of excessive electrical impedance at RF electrode 122 or 25 adjacent tissue as is discussed herein. Each RF electrode 122 is connected to resources which generate an independent output. The output maintains a selected energy at RF electrode 122 for a selected length of time.

Current delivered through RF electrode 122 is 30 measured by current sensor 140. Voltage is measured by voltage sensor 142. Impedance and power are then calculated at power and impedance calculation device 144. These values can then be displayed at user a interface and display 146. Signals representative of power and 35 impedance values are received by controller 138.

A control signal is generated by controller 138 that is proportional to the difference between an actual measured value (e.g. an analog or digital signal indicative of temperature, power, etc.) and a desired
5   value. The control signal is used by power circuits 148 to adjust the power output in an appropriate amount in order to maintain the desired power delivered at respective RF electrodes 122.

In a similar manner, temperatures detected at
10   sensor 129 provide feedback for maintaining a selected power. The temperature at sensor 129 is used as a safety means to interrupt the delivery of energy when maximum pre-set temperatures are exceeded. The actual temperatures are measured at temperature measurement
15   device 150, and the temperatures are displayed at user interface and display 146. A control signal is generated by controller 138 that is proportional to the difference between an actual measured temperature and a desired temperature. The control signal is used by power circuits
20   148 to adjust the power output in an appropriate amount in order to maintain the desired temperature delivered at the sensor 129. A multiplexer can be included to measure current, voltage and temperature, at the sensor 129, and energy can be delivered to RF electrode 122 in monopolar
25   or bipolar fashion.

Controller 138 can be a digital or analog controller, or a computer with software. When controller 138 is a computer it can include a CPU coupled through a system bus. This system can include a keyboard, a disk
30   drive, or other non-volatile memory systems, a display, and other peripherals, as are known in the art. Also coupled to the bus is a program memory and a data memory.

User interface and display 146 includes operator controls and a display. Controller 138 can be
35   coupled to imaging systems including, but not limited to,

ultrasound, CT scanners, X-ray, MRI, mammographic X-ray and the like. Further, direct visualization and tactile imaging can also be utilized.

The output of current sensor 140 and voltage sensor 142 are used by controller 138 to maintain a selected power level at RF electrode 122. The amount of RF energy delivered controls the amount of power. A profile of the power delivered to electrode 122 can be incorporated in controller 138 and a preset amount of energy to be delivered may also be profiled.

Circuitry, software and feedback to controller 138 result in process control, the maintenance of the selected power setting which is independent of changes in voltage or current, and is used to change the following process variables: (i) the selected power setting, (ii) the duty cycle (e.g., on-off time), (iii) bipolar or monopolar energy delivery; and, (iv) fluid delivery, including flow rate and pressure. These process variables are controlled and varied, while maintaining the desired delivery of power independent of changes in voltage or current, based on temperatures monitored at sensor 129.

Referring now to Figure 15, current sensor 140 and voltage sensor 142 are connected to the input of an analog amplifier 152. Analog amplifier 152 can be a conventional differential amplifier circuit for use with sensor 129. The output of analog amplifier 152 is sequentially connected by an analog multiplexer 156 to the input of A/D converter 158. The output of analog amplifier 152 is a voltage which represents the respective sensed temperatures. Digitized amplifier output voltages are supplied by A/D converter 158 to microprocessor 136. Microprocessor 136 may be a type 68HCII available from Motorola or a Pentium® type available from the Intel® Corporation. However, it will be appreciated that any suitable microprocessor or

general purpose digital or analog computer can be used to calculate impedance or temperature.

Microprocessor 136 sequentially receives and stores digital representations of impedance and temperature. Each digital value received by microprocessor 136 corresponds to different temperatures and impedances.

Calculated power and impedance values can be indicated on user interface and display 146. Alternatively, or in addition to the numerical indication of power or impedance, calculated impedance and power values can be compared by microprocessor 136 to power and impedance limits. When the values exceed predetermined power or impedance values, a warning can be given on user interface and display 146, and additionally, the delivery of RF energy can be reduced, modified or interrupted. A control signal from microprocessor 136 can modify the power level supplied by energy source 124.

Figure 16 illustrates a block diagram of a temperature and impedance feedback system that can be used to control the delivery of energy to tissue site 112 by energy source 124 and the delivery of cooling solution to RF electrode 122 and/or tissue site 112 by flow regulator 160. Energy is delivered to RF electrode 122 by energy source 124, and applied to tissue site 112. A monitor 162 ascertains tissue impedance, based on the energy delivered to tissue, and compares the measured impedance value to a set value. If the measured impedance exceeds the set value, a disabling signal 164 is transmitted to energy source 124, ceasing further delivery of energy to RF electrode 122. If measured impedance is within acceptable limits, energy continues to be applied to the tissue.

The control of the delivery of a cooling solution to RF electrode 122 and/or tissue site 112 is

done in the following manner. During the application of energy, temperature measurement device 150 measures the temperature of tissue site 112 and/or RF electrode 122. A comparator 166 receives a signal representative of the

5 measured temperature and compares this value to a pre-set signal representative of the desired temperature. If the tissue temperature is too high, comparator 166 sends a signal to a flow regulator 160 (connected to an electronically controlled micropump, not shown)

10 representing a need for an increased cooling solution flow rate. If the measured temperature has not exceeded the desired temperature, comparator 166 sends a signal to flow regulator 160 to maintain the cooling solution flow rate at its existing level.

15 The foregoing description of a preferred embodiment of the invention has been presented for purposes of illustration and description. It is not intended to be exhaustive or to limit the invention to the precise forms disclosed. Obviously, many

20 modifications and variations will be apparent to practitioners skilled in this art. It is intended that the scope of the invention be defined by the following claims and their equivalents.